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February 22, 2000

Department of Human and Health Services
Public Health Service
Commissioner of Food and Drugs
Food and Drug Administration
Documents Management Branch (HFA-305)
5630 Fishers Lane Room 1061
Rockville, MD 20852

Commissioner:

Attached is a Citizen Petition submitted in accordance with §10.20 of the Food, Drug and Cosmetic Act of 1938, as amended.

00P-0804

CITIZEN PETITION

The undersigned submits this petition under the relevant statutory sections, for example, §403(f), and §404(k) of the Federal Food, Drug and Cosmetic Act of 1938, as amended, for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10, to request that the Commissioner of Food and Drugs issue a regulation.

A. Action requested:

(1) To require the manufacturers, and/or repackers of any cucumber pickle product that contains any FD&C Yellow #5 and/or FD&C Blue #1 food colorant (dye) to place on the front panel of the label in letters the same size and color as the net weight statement, the legend, "Artificially Colored".

B. Statement of grounds:

Traditional methods of processing cucumbers to make pickles and pickle products produced a green-colored pickle product. This naturally green color remained stable for very long periods of time.

Current methods of processing cucumbers yields a pickled product that turns gray three to four months after bottling.

Because consumers would not purchase a gray pickle product, the pickle processors began to dye their pickles with FD&C Yellow #5, thus hiding the gray-appearing pickle product. The resultant pickle products were now an obvious yellow color.

As yellow pickles are not "traditionally" green colored, some pickle processors began to add FD&C Blue #1 along with FD&C Yellow #5, producing an artificially green-colored pickle product.

It is fully recognized by the petitioner that both FD&C Yellow #5, and FD&C Blue #1 are FDA "approved" food colors and may be used in pickle products and must be listed in the ingredient statement. The petitioner also recognizes that the resultant dyed pickle products now appear to be an old-fashioned, traditional green pickle product.

Unfortunately, even though the two dyes may be listed in a product's ingredient statement, the consuming public may be easily deceived into thinking that the pickle product he/she is purchasing is an "old fashioned", naturally green-colored pickle product. The purchaser may not know (or remember) that pickled cucumbers traditionally processed are naturally green, and/or may not read the ingredient statement, nor understand the significance of the additions of yellow and blue dyes to the product. The simple addition of the legend, "Artificially Colored"

on the front label panel would eliminate the possibility of a consumer being deceived into thinking that he/she is purchasing a naturally green-colored pickle product.

There is a great deal of precedent for adding descriptive legends, such as "Artificially Colored" to the front panel. A number of food processors, and/or repackers, have placed on their front label panel a descriptive statement stating that their product contains artificial colorants or ingredients. One example, is Martha White Foods, Murfreesboro, TN; on their *Wildberry Muffin Mix,* in very large letters, the legend, "Artificial Blueberry & Strawberry Flavor", and the statement, "With Artificial Blueberry & Strawberry Bits" both appear - no consumer deception there! The statement "Water Added" appears on many meat products, alerting the consumer that the meat product may leak.

C. Environmental impact:

There does not appear that there could or would be any environmental impact whatsoever caused by the proposed action of adding the legend, "Artificiality Colored" to the front panel of all pickle products that contain FD&C Yellow #5, and/or FD&C Blue #1 food dyes.

D. Economic impact:

If all pickle processors/repackers are required to place the legend "ArtificialIy Colored" on the front panel of any pickle product the industry produces containing any artificial dye colorant, and given sufficient lead time to replace their old
labels, any impact would be equal among them. Therefore, it would appear there
would be no specific adverse economic impact on the processors/repackers.

E. Certification:

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, that it is well grounded in fact and is warranted by existing laws or regulations, that it is not submitted for any improper purpose, such as to harass or to cause unnecessary delay, and that includes representative data and information known to the petitioner which are unfavorable to the petition.

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